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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/392,682 09/09/99 GRUENERT D 480.18-4

HM22/0721

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| EXAMINER |
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LEE, G

| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED:

07/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/392,682

Applicant(s)

Gruenert et al.

Examiner
Gai (Jennifer) MI Lee

Group Art Unit
1632



- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-7 *(12-17 have been renumbered 3-7)* is/are pending in the application. JDM
- Of the above, claim(s) _____ is/are withdrawn from consideration
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-7 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, 6 (16), 7 (17) are drawn to a method of gene therapy by small fragment homologous replacement, classified in class 514, subclass 44.
 - II. Claim 3 (12) is drawn to a genomic DNA sequence of human cystic fibrosis exon 10, classified in class 536, subclass 23.1.
 - III. Claim 4 (13) are drawn to a transgenic animal, classified in class 800, subclass 3.
 - IV. Claim 5 (14) is drawn to a method of targeted small fragments homologous replacement of provirus of HIV, classified in class 424, subclass 93.6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the genomic DNA sequence of human cystic fibrosis transmembrane conductance regulator gene exon 10 of invention II could be use as a probe for hybridization assays.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

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used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case invention I drawn to a method of gene therapy with small fragment homologous replacement could be use to treat without the production of a transgenic animal of invention III.

Inventions I and IV are drawn to mutually exclusive and independent methods. Invention I is to a method of gene therapy of a disease associated with a mutated DNA fragment in a subject's target cells. Invention IV is to a method of for targeted small fragments homologous replacement of provirus HIV. The two methods require separate and distinct protocols. Neither invention I or invention IV is required for implementation of the other invention.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case invention II drawn to a genomic DNA sequence of human cystic fibrosis transmembrane gene could be use as a probe for hybridization assays.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the genomic DNA sequence of human cystic fibrosis

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transmembrane conductance regulator gene exon 10 of invention II could be use as a probe for hybridization assays.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III and IV are drawn to mutually exclusive and independent inventions. Invention III is to a cystic fibrosis transgenic mouse model. Invention IV is to a method for targeted small fragment homologous replacement of provirus HIV. The transgenic mouse model require separate and distinct protocols from that of the small fragment homologous replacement of with provirus HIV. Neither invention III or IV is required for implementation of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Ms. Dolezalova on 7/13/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gai (Jennifer) Mi Lee whose telephone is (703) 306-5881. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on 703-308-2035. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Gai (Jennifer) Mi Lee
Patent Examiner
Group 1600

Ed Mart
Patent Examiner
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